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Dated: November 30, 2009 Signature: / Thomas W. Humphrey /
(Thomas W. Humphrey)

Docket No.: LF-231
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Charles S. Neer

Application No.: 10/749,894 Confirmation No.: 8901

Filed: December 31, 2003 Art Unit: 3767

For: Injector with changeable syringe constants Examiner: Maria E. Doukas

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

As required under § 41.37(a), this brief is being filed within two months of the Notice of Appeal filed on September 30, 2009, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

Liebel-Flarsheim Company

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 23 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 1-20
2. Claims withdrawn from consideration but not canceled: 41-43
3. Claims pending: 21-43
4. Claims allowed: NONE
5. Claims rejected: 21-40

C. Claims On Appeal

The claims on appeal are claims 21-40

IV. STATUS OF AMENDMENTS

On July 30, 2009, Applicant filed an Amendment after the Examiner's Final Rejection. This amendment sought to amend claim 32 to avoid the Examiner's rejection based on 35 U.S.C. 101. The Examiner's Advisory Action mailed August 11, 2009 refuses entry of this amendment, although the Examiner does not indicate any new issues raised by the amendment to claim 32, nor does the Examiner indicate that the 101 rejection would not have been overcome. Applicant

submits that the amendment of July 30, 2009 should be entered for the purposes of prosecutorial economy and has presented the claim appendix consistent with entry of this amendment.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Independent Claim 21 is described in the specification on page 8, line 1 through page 11, line 4, and Figs. 2-3, reference numbers 300, 312, 402, 408 and 410 of the drawings. As explained there, a method of operation of a motorized medical fluid injector system comprises entering a mode of the injector that permits service related functions (screen 300, step 402), receiving syringe constants while in that mode (step 408 using screen 300), calculating an additional syringe constant from the input constants (step 410, initiated with button 312) and storing the syringe definition based on the received constants and calculated constant (step 410).

B. Independent Claim 27 is described in the specification on page 8, line 1 through page 11, line 4, and Figs. 2-3, reference numbers 300, 302, 304, 306, 312, 402, 408 and 410 of the drawings. As explained there, a method of operation of a motorized medical fluid injector system comprises entering a mode of the injector that permits service related functions different from those involved in medical injection (screen 300, step 402), receiving at least three syringe constants while in that mode (step 408 using screen 300, input boxes 302, 304, 306), and storing a syringe definition based on the three constants that are received (step 410, initiated with button 312).

C. Independent Claim 32 is described in the specification on page 8, line 1 through page 11, line 4, and Figs. 2-3, reference numbers 300, 302, 304, 306, 312, 402, 408 and 410 of the drawings. As explained there, a method of operation of a motorized medical fluid injector system comprises providing a data collection routine that prompts a user to input syringe constants into the injector system (screen 300, step 402), receiving input from the user related to at least two syringe constants (step 408 using screen 300, input boxes 302, 304, 306), and updating a syringe definition based on the received input (step 410).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 32 and 35-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 21 -40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canadian Patent No. 1,329,946 to Koenig (Koenig) in view of U.S. No. 6,200,289 to Hochman (Hochman).

VII. ARGUMENT

A. Claim rejections under 35 U.S.C. 101

Applicant submits that the Examiner's rejection under 35 U.S.C. 101 should be withdrawn. Initially, Applicant notes that the Amendment After Final submitted by Applicant on July 30, 2009 should be entered to simplify issues for Appeal. However, Applicant submits that claim 32 prior to the amendment is nevertheless statutory, as its preamble states a "method of operation for a motorized medical fluid injector system" which is a statutory process as it is tied to a particular apparatus by the words of the claim. This connection to particular apparatus is made more clear by the amendment to claim 32 -- which states the "medical fluid injector" context, already found in the preamble, in the claim steps. Applicant submits that the amendment to claim 32 does not raise new issues and should be entered to more clearly establish the statutory nature of claim 32 et seq.

B. Claim rejections under 35 U.S.C. 103(a)

With respect to prior art, the Examiner has entered a rejection of all claims based upon the combination of Koenig and Hochman.

Koenig is relied upon for showing an "instrument configuration mode" which the Examiner interprets as a "service mode". Koenig shows various functions that may be performed in "instrument configuration mode". Most specifically, the Examiner notes in the

Advisory Action that the "instrument configuration mode" can be used to set "default parameters" – citing Koenig page 8, lines 11-17 and page 4, lines 19-26. The Examiner admits, however, that Koenig does not identify these "parameters".

Most important, Koenig does not indicate that the "instrument configuration mode" should be used to provide syringe constants, and/or calculate syringe constants based on input constant(s). The Examiner has conceded this point and turned to other prior art. Specifically, the Examiner relies upon Hochman, which shows an injector pump that has a memory 160 storing data banks related to syringes.

According to Hochman col. 8 line 40 et seq., an injector pump includes data banks "dedicated to the following information: (a) syringes; (b) tubing; (c) needles; (d) fluids; (e) governor parameters; and (f) profiles consisting of a plurality of parameters for a particular procedure to be performed." This noted, Hochman has no disclosure indicating that the injector has a mode for entering this information, either as part of regular operation or as part of a "service mode". Rather, Hochman describes in col. 9 that the standard operating mode of the injector includes selecting prestored syringe parameters from the data banks.

The crux of the Examiner's Final Rejection is the assertion that "[i]n storing the syringe characteristics in the data bank of Hochman, a user would have entered the values for syringe length, stroke length, and volume and then stored it as a particular definition capable of being accessed during the operational mode (col. 9, lines 23-41). Further, if syringe stroke length and volume are known, then the user would be capable of calculating an additional syringe constant." The Examiner then asserts it would have been obvious to include such a function in Koenig.

Applicant's Response After Final Rejection noted that the Examiner's assertions regarding Hochman are pure supposition, as can be seen from the use of "would have" and "would be". In fact, there is nothing to suggest that the data in Hochman's data bank comes into being from user entry, as the Examiner supposes. Hochman specifically does not describe a process for entry of the syringe parameters into the data bank, whether in a normal mode, service mode, or otherwise.

The Examiner's Advisory Action responded to this observation by asserting that "[a]lthough Hochman does not teach the user inputting the parameters (e.g. syringe length), the presence of a data bank that has this information on physical characteristics of a syringe must have been entered by a user at some point in time in order to produce this data bank."

Applicant notes that the Examiner's rejection is again arguing inherency as to the content of the Hochman prior art. Specifically, the Examiner is asserting there "must have been" user entry of syringe parameters into Hochman. In response, Applicant submits that this is not an inherent or necessarily even likely element of the Hochman prior art. The data bank shown by Hochman may well have been created at the factory and put into nonvolatile memory there – not entered by a user while in a service mode. Hochman only refers to prior entry of the data, not where and how, and it cannot be assumed that the data entry was through a "service mode". If the data bank was indeed created at the factory, e.g., using a personal computer to create data and then burn that data into read only memory, then there is no inherent disclosure of entry of the parameters using the injector, much less a "service mode" for entry of parameters, and no basis for the present rejection.

As explained in the Background of the present application, paragraph 0007, "[i]n the past, accommodating syringe variations was often difficult, time-consuming and expensive. The firmware for controlling the injector typically includes definitions of permitted syringes. Thus, any changes to the physical parameters of a syringe required entirely new firmware such as EPROMS, or other non-volatile storage, to be created which then required service personnel to visit each site having an injector in order to replace the outdated EPROM."

Notably, the Background explanation indicates that "firmware" typically contains the syringe parameters, and thus a new EPROM would be required to change parameters. The Examiner may not, therefore, assume that parameters in an injector must be there because a user typed them into a syringe interface. In fact, it is known to change syringe parameters via an EPROM substitution, in which case those parameters are never typed in to the injector interface.

Applicant submits that the Examiner's obviousness rejection must fail, as the Examiner has not shown any prior art that suggests or allows for the entry of syringe parameters in a service mode, nor has the Examiner explained a departure from the known prior art to provide such a function.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A include the amendments filed by Applicant on July 30, 2009.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23-3000, under Order No. LF-231 from which the undersigned is authorized to draw.

Dated: November 30, 2009

Respectfully submitted,

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APPENDIX A -CLAIMS

Claims Involved in the Appeal of Application Serial No. 10/749,894

1-20. (Cancelled).

21. (previously presented) A method of operation for a motorized medical fluid injector system, the method comprising:

entering a mode of the injector system that permits use of service-related functions by a service technician different from those involved in medical injection;

receiving one or more syringe constants while in the service mode;

calculating an additional syringe constant based on the inputted syringe constant(s); and

storing a syringe definition in the injector system based on the received syringe constant(s) and the calculated syringe constant.

22. (previously presented) The method of claim 21, wherein the one or more syringe constants comprises at least one of a syringe diameter, a syringe stroke length, and a syringe volume.

23. (previously presented) The method of claim 21, wherein the one or more syringe constants are selected from the group consisting of a syringe diameter, a syringe stroke length, a syringe volume, and combinations thereof.

24. (previously presented) The method of claim 21, further comprising:

updating a software routine within the injector system which relies on the syringe definition.

25. (previously presented) The method of claim 21, further comprising:

exiting the service mode; and

entering an operation mode for use in medical procedures whereby a medical procedure involving injection may be executed.

26. (previously presented) The method of claim 25, wherein the operational routine relies on the syringe definition.

27. (previously presented) A method of operation for a motorized medical fluid injector system, the method comprising:

entering a mode of the injector system that permits use of service-related functions by a service technician different from those involved in medical injection;

receiving at least three syringe constants while in the service mode; and

storing a syringe definition in the injector system based on the at least three syringe constants that are received.

28. (previously presented) The method of claim 27, wherein the at least three syringe constants are a syringe diameter, a syringe stroke length, and a syringe volume.

29. (previously presented) The method of claim 27, further comprising:
updating a software routine within the injector system which relies on the syringe definition.

30. (previously presented) The method of claim 27, further comprising:

exiting the service mode; and

entering an operation mode for use in medical procedures whereby a medical procedure involving injection may be executed.

31. (previously presented) The method of claim 30, wherein the operational routine relies on the syringe definition.

32. (previously presented) A method of operation for a motorized medical fluid injector system, the method comprising:

providing a data collection routine of the medical fluid injector system that prompts a user to input syringe constants into the injector system;

receiving input from the user into the medical fluid injector system related to at least two syringe constants; and

updating a syringe definition based on the received input.

33. (previously presented) The method of claim 32, further comprising:

storing the syringe definition in a non-volatile memory of the injector system.

34. (previously presented) The method of claim 33, further comprising:

deleting another syringe definition from the non-volatile memory.

35. (previously presented) The method of claim 32, wherein the at least two syringe constants comprises two or more of a syringe diameter, a syringe stroke length, and a syringe volume.

36. (previously presented) The method of claim 32, further comprising

calculating another syringe constant based on the input relating to the at least two syringe constants.

37. (previously presented) The method of claim 32, further comprising:

modifying one or more medical functions for injecting fluid using the injector system affected by the updating.

38. (previously presented) The method of claim 32, further comprising:

modifying one or more parameters used in calibration of the injection of fluid, that are stored by the injector system and affected by the updating.

39. (previously presented) The method of claim 32, further comprising:

associating a label with syringe information based on the received input.

40. (previously presented) The method of claim 32, wherein the updating comprises:

modifying an existing syringe definition; or

creating a new syringe definition.

41. (withdrawn) A contrast media injector system comprising:

a processor;

a non-volatile storage coupled with the processor;

an application stored within the non-volatile storage configured to execute on the processor, the application including:

an input routine configured to:

enable a user to input at least two syringe constants;

determine an omitted syringe constant; and

calculate the omitted syringe constant; and

an updating routine configured to modify an existing syringe definition or create a new syringe definition based on the received data.

42. (withdrawn) The injector system of claim 41, wherein the existing syringe definition or the new syringe definition is stored in the non-volatile storage.

43. (withdrawn) The injector system of claim 41, further comprising:

another application that is stored in the non-volatile storage and that comprises one or more control routines to operate the injector system, wherein the control routines may utilize the existing syringe definition or the new syringe definition to operate the injector system.

APPENDIX B- EVIDENCE

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

APPENDIX C- RELATED PROCEEDINGS

No related proceedings are referenced in II. above, hence copies of decisions in related proceedings are not provided.